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Counting rules and out-of-pocket payment under Japan's 2026 high-cost medical expense reform: a simulation of breast cancer treatment courses

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Research Article

Keywords: high-cost medical benefit, cost sharing, out-of-pocket payment, catastrophic health expenditure, health policy simulation

Posted Date: November 13th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11410504/v1

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Counting rules and out-of-pocket payment under Japan's 2026 high-cost medical expense reform: a simulation of breast cancer treatment courses

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Author contributions: Conceptualization: all authors. Formal analysis: Akemi Hara. Data curation: Akihiko Ozaki, Masahiro Wada, Masanori Oshi, Kazunoshin Tachibana, Mika Nashimoto. Writing – original draft: Akemi Hara and Akihiko Ozaki. Writing – review and editing: all authors.

Abstract

Background. Japan's high-cost medical benefit caps monthly out-of-pocket payment by income and lowers the cap from the fourth qualifying month. The August 2026 reform raised the monthly caps, kept the lower cap, and added an annual cap over a fixed August–July year. We estimated its effect on what breast cancer patients pay.

Methods. We simulated 15 courses before and after the reform by income category, start date, and brand or generic pricing. The benchmark was the increase for a patient who reaches the monthly cap every month: three months' rise in the cap, 4,500 to 51,330 yen (US$28–323) across five income categories.

Results. Of 60 combinations of one-year course and income category, payment was unchanged in 16, mostly endocrine courses; rose by no more than the benchmark in 26, mostly surgery and chemotherapy courses; and rose or fell with the course start in 18. The increase exceeded the benchmark in 8 of the 60, 7 in the two highest categories and none in the two lowest, reaching 409,840 yen (US$2,578) against a benchmark of 51,330 yen (US$323). Decreases, up to 664,647 yen (US$4,180), came only from the annual cap, reached in 1,423,481 of 21,475,422 course-years. Generic or biosimilar substitution, though cheaper, raised the annual payment in 23.30% of 51,873 upper-middle-category pairs (median across start days).

Conclusions. The reform adds little or nothing for endocrine treatment, surgery, and standard chemotherapy. For year-long high-cost courses, the effect depends on income and start month, and a cheaper drug can cost the patient more.

Keywords

high-cost medical benefit; cost sharing; out-of-pocket payment; catastrophic health expenditure; health policy simulation

1. Introduction

Catastrophic health expenditure, spending large enough relative to a household's means to displace necessities or force borrowing, is what cost-sharing ceilings are meant to prevent [1]. Health systems increasingly provide this protection with a ceiling on out-of-pocket payment, and they adjust that ceiling rather than leave it fixed. Germany caps a household's annual

copayments at 2% of gross income, and at 1% for people with severe chronic illness [2]. South Korea applies an income-tiered annual copayment ceiling that it revises over time [3]. The United States added an annual out-of-pocket maximum to Medicare Part D in 2024 and lowered it to $2,000 the next year [4].

What these ceilings do for patients has been studied mainly through access, spending, and financial protection. In the United States, the Part D cap raised the use of high-cost medications [4], while plans raised deductibles and coinsurance so that beneficiaries who never reach the cap can pay more than before [5]. In Korea, the ceiling increased utilization but did not clearly reduce catastrophic payments among cancer patients and reached only a small share of them [3]. In Japan, the out-of-pocket burden on patients with cancer has been measured with patient-reported instruments [6,7], while studies of catastrophic health expenditure ask who crosses an affordability threshold [8]. Changes to a ceiling are announced as new cap amounts, yet whether a patient's payment over a whole course of treatment changes by that amount, and for which treatments and incomes it does not, has rarely been examined in any system. The answer depends on the rules by which a benefit adds up spending, across the month, the provider, and the reference year, and those rules are usually taken as given.

Japan's universal insurance has capped monthly out-of-pocket payment since 1973 through the High-Cost Medical Expense Benefit, which refunds spending above an income-set monthly limit [9]. The reform that took effect in August 2026 grew out of a debate about how to pay for the benefit [10,11]: it raises the monthly caps, adds a further step in 2027, and for the first time introduces an annual cap settled over a year fixed to run from August to July, while leaving the repeat-month cap largely unchanged [12,13]. Breast cancer treatment, which combines high monthly drug costs with courses lasting from a single month to more than two years, spans the range over which these boundaries fall, so we use it as the material although

the rules apply to every disease [14,15]. In employees' health insurance it is also among the costliest cancers, taking about the fifth-largest share of total medical spending and the third-largest of inpatient spending in January 2026 claims [16].

Because every parameter is fixed in law, the reform offers a clean case to add to this international evidence. This study aimed to estimate how the 2026 reform changes what a patient with breast cancer pays over a course of treatment, and how that change differs by treatment course and income category. The primary aim was to compare the change in out-of-pocket payment, after the reform minus before it, with the increase implied by the higher monthly caps alone, for 15 treatment courses in each income category. The secondary aims were to identify the rules that make the change larger or smaller than that amount, and to establish whether, under the reformed rules, switching to a cheaper generic or biosimilar can raise what a patient pays for the year. The novelty lies in following the reform through whole courses of treatment rather than through cap amounts.

2. Materials and Methods

2.1 Study background

The study has no patient sample and no individual-level data. For each treatment profile we generate every administration, test, outpatient visit, dispensing, and inpatient day as an event carrying a date, cost it at national tariff, and attribute it to the calendar month containing that date. One combination of the levels listed under Variables gives one series of monthly costs. Institutional parameters come from the amending Cabinet Order [12] and the corresponding Ministerial Ordinance [17]; unit prices from the national drug price list [15] and the fiscal 2026 medical procedure master [18]; clinical content from a review by breast surgeons and medical oncologists (Appendix section A.10). The computation is deterministic and makes no random draw. Appendix sections A.1 to A.3 give the statutory derivation, the profile specifications, and the cost build-up (Tables A1–A6).

The 15 courses run from surgery alone through a year of human epidermal growth factor receptor 2 (HER2)-targeted or antibody-drug-conjugate treatment to 24 months of oral cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitor therapy. Twelve are followed for 12 months (profiles P1 to P12, the main path) and the three CDK4/6 courses for 24 months. Table A6 summarises each in one line and Table A1 gives the full specification.

Under Article 42(1) of the Enforcement Order [19], the monthly cap is a fixed component plus 1% of total medical expenditure above a reference amount that equals the fixed component divided by 0.3; below that reference amount the cap does not bind and the patient pays the full 30%. The repeat-month cap applies from the fourth month in the rolling 12 months in which benefit was paid. The annual cap, set by Article 42(11) and conditioned by Article 41-3 [19], is settled retrospectively for the household over a fixed 1 August to 31 July year, and for those under 70 only charges of 21,000 yen (US$132) or more incurred in the same month at the same provider are aggregated (Enforcement Regulation, Article 109(1)(ii) [20]). Each course is computed as the only care in its household. Tables A7–A8 and Fig. A1 give these parameters before and after each reform step and follow one course through them; Appendix A.4–A.5 give the series construction and the order in which the instruments are applied.

2.2 Outcome

The outcome is the change in out-of-pocket payment over the course: the payment after the reform minus the payment before it, in Japanese yen (converted at US$1 = 159 yen, approximately the August 2026 average), so that a positive value is an increase in what the patient pays. It is a continuous quantity, computed for every course start in each of the five 2026 income categories, a course start being one series begun on one of 24 start dates (the 1st or the 15th of each calendar month). For each profile and income category it is summarised by the median, the minimum, and the maximum (Table 1).

The change is read against a benchmark increase. The reform raised the monthly cap and left the repeat-month cap unchanged, so a patient who reaches the monthly cap pays the higher amount in the first three qualifying months, after which the unchanged repeat-month cap applies. The benchmark is three times the rise in the monthly cap for the category (Table A7).

Three further measures describe where the change departs from the benchmark. The first is the share of treatment-months (one month of one series) whose bill lies in the range where the coinsurance amount is at or above the repeat-month cap but the monthly cap does not apply (the between-caps range). Such a month does not qualify, and the count that governs the repeat-month cap does not advance. A treatment phase is designated when that share is 0.50 or greater in the 2026 middle-income category in the base stratum (follow-up frequency and body size at their middle levels; Appendix section A.6.3). The second is annual-cap attainment, the share of course-years (one August–July year of one series) in which the aggregate exceeds the cap (Table 1). The third is the proportion of brand-and-generic series pairs whose annual out-of-pocket payment is higher in the generic arm, for an August start on each day from the 1st to the 28th, designated as present in an income category at 0.1% or greater. The first and third are the two measures whose definitions and thresholds were fixed in advance (Appendix sections A.6.3 and A.6.4). Table A9 gives the unit and denominator of every quantity, and the Glossary defines every term.

2.3 Variables

The exposure is the reform: every course is evaluated under the rules before it and under each of its two steps. Calendar start month and income category are dimensions of the design, enumerated and reported across rather than averaged over. The strata crossed within a profile cover the surgical procedure and tests, fee-schedule add-ons, body size (bracketed from national height and weight statistics [21]), supportive-care regimens, cytotoxic and antibody-drug-conjugate schedules, follow-up frequency, the maintenance dispensing interval, and the

start day; Appendix section A.7.1 lists every axis and its levels. The enumeration comprises 51,873 series per pricing arm, each evaluated at all 12 calendar start months and all 18 income categories under both parameter sets (Table A3). In the brand arm every drug is priced at the originator product. In the generic arm the twelve injectable ingredients of the selection table, including trastuzumab, are priced at a listed generic or biosimilar where one exists; oral agents, the ovarian-suppression depot, and denosumab keep the brand price (Appendix section A.3.2). Primary prophylaxis with granulocyte colony-stimulating factor is counted only for regimens with febrile neutropenia risk of about 20% or higher [22].

2.4 Statistical analysis

Sensitivity analyses cover the induction-to-maintenance switch point of the CDK4/6 inhibitors, the neoadjuvant regimen of the post-neoadjuvant profile, the length of inpatient stay, and a 28-point sweep of the start day. A counterfactual, specified after the other results had been computed, counted the annual cap over a rolling 12-month window that opens at each course’s first qualifying month. The proportions against which the two thresholds are applied are given in Table A10 and Table 2.

Correctness was checked against implementations written separately from the analysis engine (Tables A11 and A12). Appendix sections A.6 to A.9 give the outcome definitions, the sensitivity analyses, the reproducibility record, and the items left undetermined (Tables A13–A19). All computations were performed in Python version 3.13.9.

3. Results

3.1 Change in payment by treatment course and income category

Table 1 shows the change in out-of-pocket payment for the twelve one-year courses in each of the five 2026 income categories, A (highest) to E (municipal-tax-exempt), and the share of years in which each course reached the annual cap. Of the 60 combinations of course and category, payment was unchanged at every course start in 16. These were the three endocrine-

based courses (P5, P11, P12) in nearly every category, and surgery alone and ductal carcinoma in situ in Category A. In 26 combinations the payment rose or stayed the same and never fell, and the increase never exceeded the benchmark. Increases for the surgical and chemotherapy courses (P1–P4) ran from 1,500 yen (US$9) in Category E to 17,110 yen (US$108) in Category A. The two HER2-positive adjuvant courses (P6, P7) in Categories D and E had an increase equal to the benchmark, 11,700 and 4,500 yen (US$74 and US$28), at every course start. In the remaining 18 combinations the reform raised the payment at some course starts and lowered it at others. These were the HER2-positive adjuvant courses in Categories B and C and the three most intensive courses (P8–P10) in nearly every category. For the triple-negative neoadjuvant course in Category A the change ran from a decrease of 624,087 yen (US$3,925) to an increase of 409,840 yen (US$2,578).

The increase exceeded the benchmark in eight combinations: five courses in Category B (P6–P10), two in Category A (P8, P10), and one in Category C (P6). The largest increase was 409,840 yen (US$2,578) against a benchmark of 51,330 yen (US$323) in Category A, and 279,189 yen (US$1,756) against 33,930 yen (US$213) in Category B. Every course start above the benchmark contained a month whose bill lay between the old and the new amount at which the monthly cap begins to apply (Table A7). That month reached the cap before the reform and not after it, so it no longer qualified, and the repeat-month cap applied in fewer of the months that followed.

Every decrease arose at a course start that reached the annual cap, and the largest decrease on the main path was 664,647 yen (US$4,180), for the metastatic antibody-drug conjugate course in Category A. Over the main path the cap was reached in 1,423,481 of 21,475,422 course-years (6.63%; Table A9). Attainment was confined to five profiles (P6–P10), highest in the triple-negative neoadjuvant profile (22.5% of its years) and the post-neoadjuvant profile (16.3%); the other seven never reached it.

3.2 The between-caps range

Fig. 1 shows the between-caps range, in which the 30% coinsurance lies between the repeat-month cap and the monthly cap. The reform raised its upper end and left the lower end unchanged, so the range widened in all five categories (Table A7). In the 2026 middle category in the base stratum, the share of anti-HER2 maintenance months inside it was 0.600 at a day-1 start, and zero in every other treatment phase (Table A10). The 0.50 threshold was met in 2026 Category C and in 2027 Categories 7, 8, and 9 (Table A18).

3.3 The calendar start month and the annual cap

Fig. 2 shows, for all twelve main-path profiles, the number of income categories in which the annual cap was reached, by the calendar month in which treatment started. Of the 216 profile-by-category combinations, 72 reached the cap in at least one August–July year. All 72 could reach the cap when treatment began in August, the first month of the fixed August–July year; the count fell month by month to zero for a March start and recovered through July. Take one course of the metastatic antibody-drug conjugate profile in 2027 Category 1, the highest income category (Table A12). Started in August, it reaches the annual cap and pays 1,680,000 yen (US$10,566) over the twelve-month period. The same course started in March is split across two years and reaches the cap in neither. It pays 2,496,145 yen (US$15,699), 816,145 yen (US$5,133) more, for the same care at the same total cost.

3.4 Generic or biosimilar substitution

Table 2 shows the proportion of brand-to-generic pairs whose annual payment rose on switching. It met the 0.1% threshold in eight of the 18 income categories, which together cover standard monthly remuneration (the graded wage that sets the income category) from 280,000 to below 830,000 yen (US$1,761 to below US$5,220). Over the 28 start days, the median proportion of the 51,873 pairs was 0.2330 in the 2026 upper-middle category and its 2027 counterpart, with a maximum of 0.2899, and 0.0743 to 0.0790 in the other six. The ten

other categories were zero at every start day. The largest single-pair increase was 263,410 yen (US$1,657). Switching never raised annual total expenditure: the generic arm's total was lower in 50,220 pairs and equal in 1,653 (Table A9).

3.5 Supplementary analyses: CDK4/6 courses and a rolling window

Fig. A2 and Table A20 show the three CDK4/6 profiles, followed over 24 months with 14-day dispensing during induction and 28-day dispensing thereafter. Under the base switch point, all 432 combinations of each of the three reached the annual cap in at least one August–July year. The difference over the 24-month course was negative in about three-quarters of combinations and positive in the rest, all in October-to-June starts and nearly all in the middle and lower categories. The upper-middle-category medians were large decreases, from about 630,000 to 1,060,000 yen (US$3,962–6,667) across the three profiles; the middle-category adjuvant median was an increase of 13,730 yen (US$86), also its maximum (Table A20). With 90-day dispensing, kept as an outlier scenario, the adjuvant profile in the middle category reached the cap at no start month and its payment rose by 16,530 yen (US$104) at every one (Fig. A3).

Table A21 compares the fixed year with the rolling window. Over the main path, the courses reaching the annual cap rose from 1,423,481 to 4,105,929 of 11,204,568 (12.7% to 36.6%; under the fixed year this is 1,423,481 of 21,475,422 course-years, since a course started outside August spans two years). The combinations of series and income category in which the start month decided the sign of the change fell from 215,008 to 18,893 of 933,714. For the three CDK4/6 profiles, the courses reaching the cap fell from 648 to 540 of 648 (100% to 83.3%).

4. Discussion

4.1 Main findings

For endocrine treatment, surgery, and standard chemotherapy, the 2026 reform means a small increase in what a patient pays, or none. The exceptions are the courses built on a year of high-cost drugs: anti-HER2 treatment, antibody-drug conjugates, and the triple-negative neoadjuvant regimen. For these the reform does not have one effect. In the two lowest income categories the payment rises by no more than the benchmark, 11,700 or 4,500 yen (US$74 or US$28), and sometimes falls. In the two highest it can rise by several times the benchmark or fall by hundreds of thousands of yen, and which of these happens is decided by details that no patient or clinician chooses.

The larger increases come from a part of the benefit the reform did not change. A month counts toward the lower repeat-month cap only if its bill is high enough for the monthly cap to apply. The reform raised that amount and left the repeat-month cap where it was, so a month just under the new amount now pays the full 30% and no longer counts (Fig. 1). A patient who used to reach the repeat-month cap after three such months may now reach it later or not at all, and pays more in the months that follow. This is how a rise of 11,310 yen (US$71) in a monthly cap can become an increase of more than 150,000 yen (US$943) over a course (Table 1). It falls on the two highest income categories, whose caps begin to apply only around 600,000 and 900,000 yen (US$3,774 and US$5,660) a month, amounts a month of these courses can reach.

Earlier work has shown that the timing of cost sharing changes what patients spend and pay: a simulation found that adding monthly out-of-pocket caps to high-deductible plans substantially raises their actuarial value [23], and US studies describe the jumps in cost a patient meets as spending crosses thresholds within a single year [24–26]. Our finding sits elsewhere. Within any one month the payment rises smoothly with the bill; the mismatch

appears only when spending is counted across months, across providers, and across the fixed year. The annual cap is where this shows most clearly, and it was designed for the very patients it can miss. The Ministry introduced it for patients on long treatments who never trigger the repeat-month cap, giving the example of a middle-income patient paying 70,000–80,000 yen (US$440–503) in ten months of the year [13]. The anti-HER2 maintenance phase in Fig. 1 is that patient, yet whether the cap ever helps them depends on the month they started (Fig. 2). Where the cap is reached it can more than offset the higher monthly caps: every decrease in Table 1 is an annual-cap refund. For the multi-year oral CDK4/6 courses it is always reached, with large decreases in the upper-middle category and small increases in the middle one (Table A20).

Treating patients with the same income differently is what health economists call horizontal inequity [27]; the dependence on the starting month creates it even for identical treatment. That a cheaper product can raise the yearly payment (Table 2) also sets these counting rules against national policy, which has targets for generic and biosimilar use by fiscal 2029 [28]. The paradox comes entirely from how months are counted. The yearly payment rose only when a cheaper month fell below the level at which the monthly cap starts to apply, or below the 21,000-yen (US$132) threshold, so that it no longer counted toward the repeat-month cap or the annual cap. In the United States, out-of-pocket costs for biologics fell after biosimilars entered Medicare [29] but not always under commercial insurance [30]; here, a switch that lowers the insurer's cost can raise the patient's.

The fixed August-to-July year is borrowed from an existing rule, the annual cap on outpatient payments for people aged 70 and over (Article 41-2 [19]). A window that instead opens at each patient's first qualifying month would remove most of the dependence on the calendar (Table A21). It would lower attainment in the CDK4/6 courses, because a window that opens only at a qualifying month never opens when no single month is large enough to trigger the

benefit. Such a window could reuse an existing count, since the repeat-month cap is already counted over the most recent twelve months. The fixed year's advantage is simple settlement against a single reference date and income band; a rolling window would need a per-patient settlement date and a rule fixing the income band at the start.

For clinical practice these findings change what can be said to a patient about cost. A patient in the two lowest income categories starting a year of adjuvant anti-HER2 treatment can be told the increase in advance. For a patient in the upper income categories starting an intensive course, neither the regimen nor the income category is enough to say whether the reform will cost or save money. That depends on individual monthly bills and on the calendar month of the first treatment, which cannot be chosen around a refund. Because the annual cap is paid only on application [13], these are also the patients who most need to be told that a refund may be due.

4.2 Limitations

Several limits apply. We cost each treatment as if given in full, so dose reductions, delays, early stopping, and admissions for complications, all of which would shift monthly totals, are not modelled. Other care costing 21,000 yen (US$132) or more at one provider would count toward both the monthly and annual totals, lifting some months above the level at which the monthly cap applies and making the annual cap easier to reach, as would a longer horizon. The 21,000-yen (US$132) floor is applied under one of the two readings the regulation allows; the other was bounded rather than computed. We assume every annual-cap refund due is claimed and paid [13], so ours may exceed those actually received. Inpatient care is costed item by item, so payments at the 1,767 hospitals paid under the bundled per-diem system may differ [31]. The comparison with the benchmark was defined after the first results had been seen; the measures fixed in advance and other choices made without an outside anchor are listed in Appendix A.6, A.7, and A.9. All were recorded in dated analysis code rather than a

public registry, so their priority can be audited but not independently certified. Only the rolling window was computed as an alternative design; the case for re-examining the per-provider threshold rests on the mechanism shown here. Finally, the unit is a constructed treatment series, not a real patient, so the results show where the rules break, not how many patients each break would affect.

4.3 Conclusions

The 2026 reform raises the payment for endocrine treatment, surgery, and standard chemotherapy by a small and predictable amount or not at all, but for intensive courses in the upper income categories its effect ranges from a large increase to a large decrease, depending on how the cost of care happens to fall across months, providers, and the fixed August-to-July year. Two changes would loosen that dependence without changing any cap amount: replace the fixed year with a rolling twelve-month window starting at the patient's first qualifying month, as the repeat-month count already works, and re-examine the per-provider monthly threshold, which drops the cheapest months from the annual total and is one way a cheaper generic or biosimilar ends up raising the yearly payment. Each can be checked in claims data once the first August-to-July year closes after July 2027. Although shown here on Japan's reform, these are design lessons for any capped benefit that adds up spending over fixed boundaries.

Figures and tables

Fig. 1. The monthly layer in each 2026 income category and one series against it. (a–e) Out-of-pocket payment as a function of the month's total medical expenditure in 2026 Category A (highest, a), B (upper-middle, b), C (middle, c), D (lower, d), and E (municipal-tax-exempt, e): in an ordinary month before the reform (dashed line), in an ordinary month after the reform (solid line), and in a month in which the repeat-month cap, the lower cap that applies from the

fourth qualifying month, is in force (dotted line). The shaded band is the between-caps range, in which the 30% coinsurance lies between the repeat-month cap and the monthly cap: a month inside it pays the full 30% coinsurance and does not count toward the repeat-month cap (Appendix section A.6.1). Its endpoints, printed in each panel, are the repeat-month cap and the fixed component of the monthly cap, each divided by 0.3. Panels a to e are determined by the statutory parameters alone (Table A7) and contain no simulated series. (f) Monthly total medical expenditure of one human epidermal growth factor receptor 2 (HER2)-positive adjuvant series (P6) in the base stratum, August day-1 start; the shaded band and horizontal lines mark the Category C between-caps range. Amounts are in Japanese yen (US$1 = 159 yen).

Fig. 2. The calendar start month decides whether the cap can engage. Number of income categories, of 18, in which the annual cap is reached in at least one August–July year, by main-path profile (P1 to P12, Table 1) and calendar start month; the bottom row gives the count of reaching profile-by-category pairs, of 216. The seven profiles in which no year reaches the cap are shown as rows of zeros. An August start is the only one that leaves a 12-month course undivided by the year boundary. The three cyclin-dependent kinase 4 and 6 (CDK4/6) profiles are not shown, because the quantity reported for them is the difference over the whole 24-month course rather than attainment by year; they appear in Fig. A2.

Table 1. Change in out-of-pocket payment over the course after the reform, by treatment course and 2026 income category, and annual-cap attainment*

Profile	Years (%)	Category A (benchmark 51,330)	Category B (benchmark 33,930)	Category C (benchmark 16,530)	Category D (benchmark 11,700)	Category E (benchmark 4,500)
Surgery alone (P1)	0.0	0 [0, 0]	5,655 [0, 11,310]	5,510 [5,510, 5,510]	3,900 [3,900, 3,900]	1,500 [1,500, 1,500]
Ductal carcinoma in situ (P2)	0.0	0 [0, 0]	5,655 [0, 11,310]	11,020 [11,020, 11,020]	7,800 [7,800, 7,800]	3,000 [3,000, 3,000]
Surgery and adjuvant chemotherapy (P3)	0.0	7,170 [0, 17,110]	11,310 [0, 11,310]	5,510 [5,510, 5,510]	3,900 [3,900, 3,900]	1,500 [1,500, 1,500]
Surgery, chemotherapy, radiotherapy (P4)	0.0	7,170 [0, 17,110]	11,310 [0, 11,310]	11,020 [11,020, 11,020]	7,800 [7,800, 7,800]	3,000 [3,000, 3,000]
Endocrine monotherapy (P5)	0.0	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]
HER2-positive adjuvant, intravenous (P6)	4.2	17,110 [0, 34,220]	33,930 [−125,606, 188,243]**	16,530 [−20,173, 60,557]**	11,700 [11,700, 11,700]	4,500 [4,500, 4,500]
HER2-positive adjuvant, subcutaneous (P7)	4.3	17,110 [0, 34,220]	33,930 [−114,758, 183,515]**	16,530 [−19,443, 16,530]	11,700 [11,700, 11,700]	4,500 [4,500, 4,500]
Post-neoadjuvant, residual disease (P8)	16.3	34,220 [−394,008, 238,508]**	33,930 [−307,505, 279,189]**	16,530 [−76,557, 16,530]	11,700 [2,000, 11,700]	4,500 [−13,000, 4,500]
Metastatic antibody-drug conjugate (P9)	12.5	34,220 [−664,647, 51,330]	33,930 [−252,697, 212,100]**	16,530 [−142,127, 16,530]	11,700 [−42,400, 11,700]	4,500 [−37,600, 4,500]
Triple-negative neoadjuvant (P10)	22.5	140,867 [−624,087, 409,840]**	−16,110 [−435,408, 182,685]**	16,530 [−127,929, 16,530]	11,700 [−42,400, 11,700]	4,500 [−37,600, 4,500]
Endocrine with bone-modifying agent (P11)	0.0	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 320]
Premenopausal endocrine with ovarian suppression (P12)	0.0	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]

* All amounts are in Japanese yen (US$1 = 159 yen). Each cell gives the median, with the minimum and maximum in brackets, of the change in out-of-pocket payment over the course (post-reform minus pre-reform) across all series of the profile and 24 start dates (the 1st or the 15th of each calendar month), in the brand arm; a negative value is a decrease in what the patient pays. Where the number of values is even and the two middle values differ, the median is their midpoint. The benchmark is three times the rise in the monthly cap for the category (Table A7). Every decrease arose at a course start that received an annual-cap refund. Years (%) is the share of August–July years in which the cumulative aggregate exceeded the cap, over all series and the 12 calendar start months at a day-1 start, in all 18 income categories of both reform steps (Table A9). The limitations in section 4 apply.

** The maximum exceeds the benchmark. In every course start whose increase exceeded the benchmark, at least one month had a total medical expenditure between the reference amounts before and after the reform (Table A7), and the repeat-month cap applied in fewer months after the reform than before it.

Table 2. Brand-to-generic pairs in which substitution raised the annual payment, over the 28-point start-day sweep, by income category*

Income category	Median	Minimum	Maximum	Largest (JPY)
2026 Category B (upper-middle) and 2027 Category 6	0.2330	0.0468	0.2899	263,410
2026 Category C (middle) and 2027 Categories 7, 8, and 9	0.0790	0.0370	0.2054	12,989
2027 Category 4	0.0761	0.0358	0.1961	12,989
2027 Category 5	0.0743	0.0349	0.1896	12,989
All ten other categories	0.0000	0.0000	0.0000	n.a.

* Largest is the largest single-pair increase in Japanese yen (US$1 = 159 yen); n.a. denotes no qualifying pair. Median, Minimum, and Maximum are proportions over the 28-point start-day sweep. Proportions are of all 51,873 brand-to-generic pairs; excluding the 1,653 equal-expenditure pairs multiplies each value by 1.033 and changes no designation. The eight designated categories cover standard monthly remuneration from 280,000 to below 830,000 yen (US$1,761 to below US$5,220). The four categories grouped in the second row (2026 Category C together with 2027 Categories 7, 8, and 9) agree exactly at every one of the 28 start days and in the largest single-pair increase; for two of them this is expected, since their parameters are identical, while the other two differ in the fixed component and share only the repeat-month cap and the annual cap, so their agreement is an observed coincidence at this level of the design rather than evidence that the fixed component is irrelevant. The designated set is conditional on the base neoadjuvant arm of the post-neoadjuvant profile, a design assumption fixed in advance; under the sensitivity arm the designation extends to the highest income category of 2026 and the top three of 2027, at day-1 proportions of 0.0162 to 0.0294, carried entirely by that profile’s pairs. The day-1 base is the sweep minimum in six of the eight designated categories and ranks fourth of 28 in the other two.

Declarations

Acknowledgments. The authors thank Yuichi Watanabe (Institute of Developing Economies, Japan External Trade Organization) for helpful comments on the economic analysis.

Funding. This study received no funding.

Conflict of interest. Kazunoshin Tachibana has received lecture fees and related travel support from Taiho Pharmaceutical, Eli Lilly Japan, Chugai Pharmaceutical, AstraZeneca, Kyowa Kirin, PDRadiopharma, Eisai, Pfizer, Daiichi Sankyo, MSD, Teijin Healthcare, Exact Sciences, and Hair Clinic Reve-21; holds a Grant-in-Aid for Scientific Research (C) from the Japan Society for the Promotion of Science (26K13544), paid to his institution and unrelated to the present work; and serves as an unpaid member of the Quality Assurance Committee of Breast Cancer Screening, Fukushima Preservative Service Association of Health. All other authors declare that they have no conflict of interest.

Ethical approval. This article does not contain any studies with human participants or animals performed by any of the authors.

Data availability. The analysis code, the registered parameter files, the generated monthly series and result tables, and the decision record (the dated claims ledger, the phase log, and the final pre-registration) are available from the corresponding author on reasonable request. The decision record is retained because the priority of thresholds and definitions over results is stated above to be auditable but not independently certified, and the log is what lets a reader carry out that audit. All primary inputs are already public and are cited in the reference list: the amending Cabinet Order and Ministerial Ordinance [12,17], the national drug price list [15], the fiscal 2026 medical procedure master [18], the Enforcement Order and Enforcement Regulation [19,20], and the national health and nutrition statistics [21].

Use of generative artificial intelligence. The authors used Claude (Opus 5, Anthropic) to draft and revise the text of the manuscript and appendix and to write and execute the analysis code. The authors reviewed and verified all content, including every number and reference, and take full responsibility for it.

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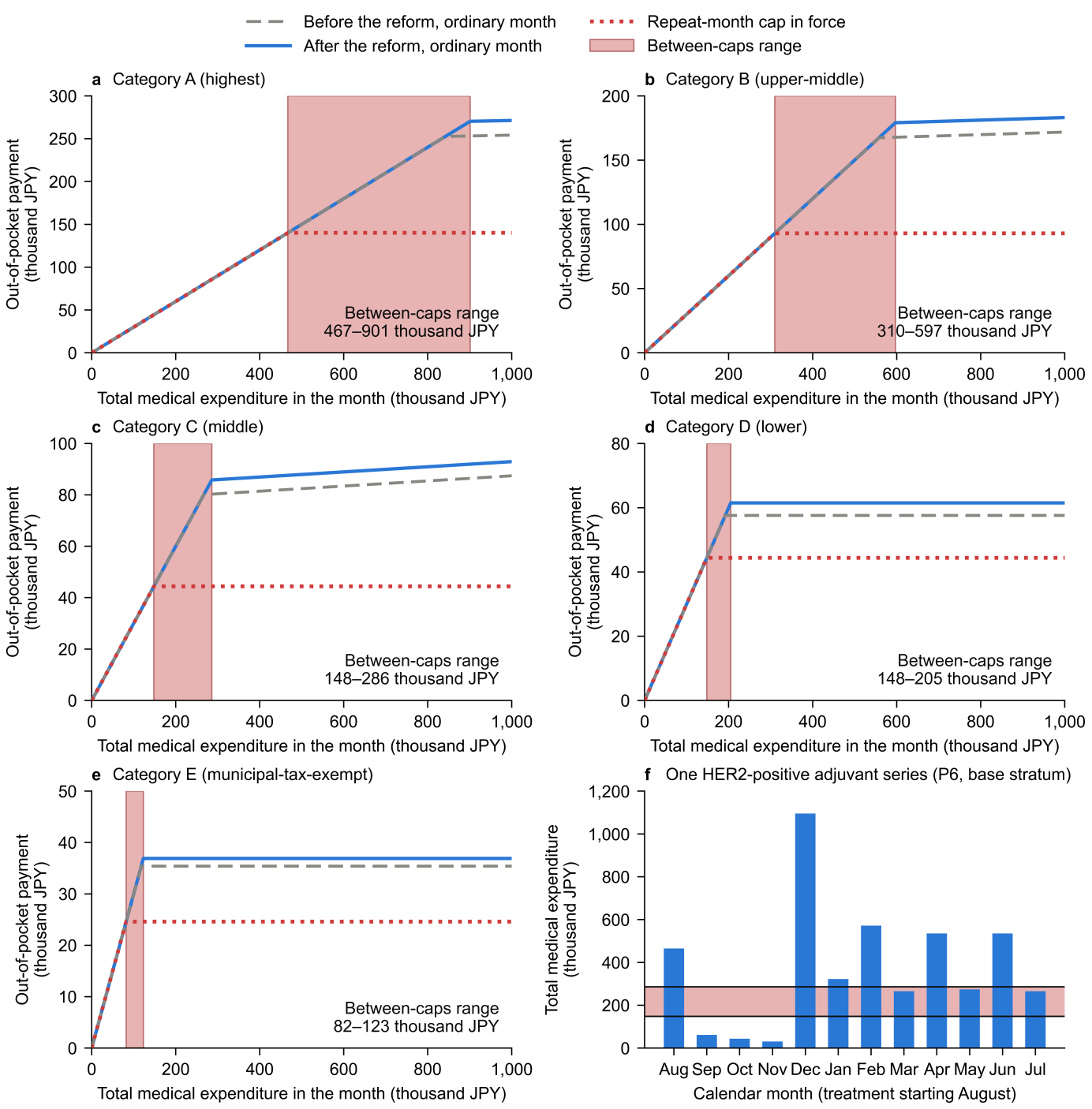
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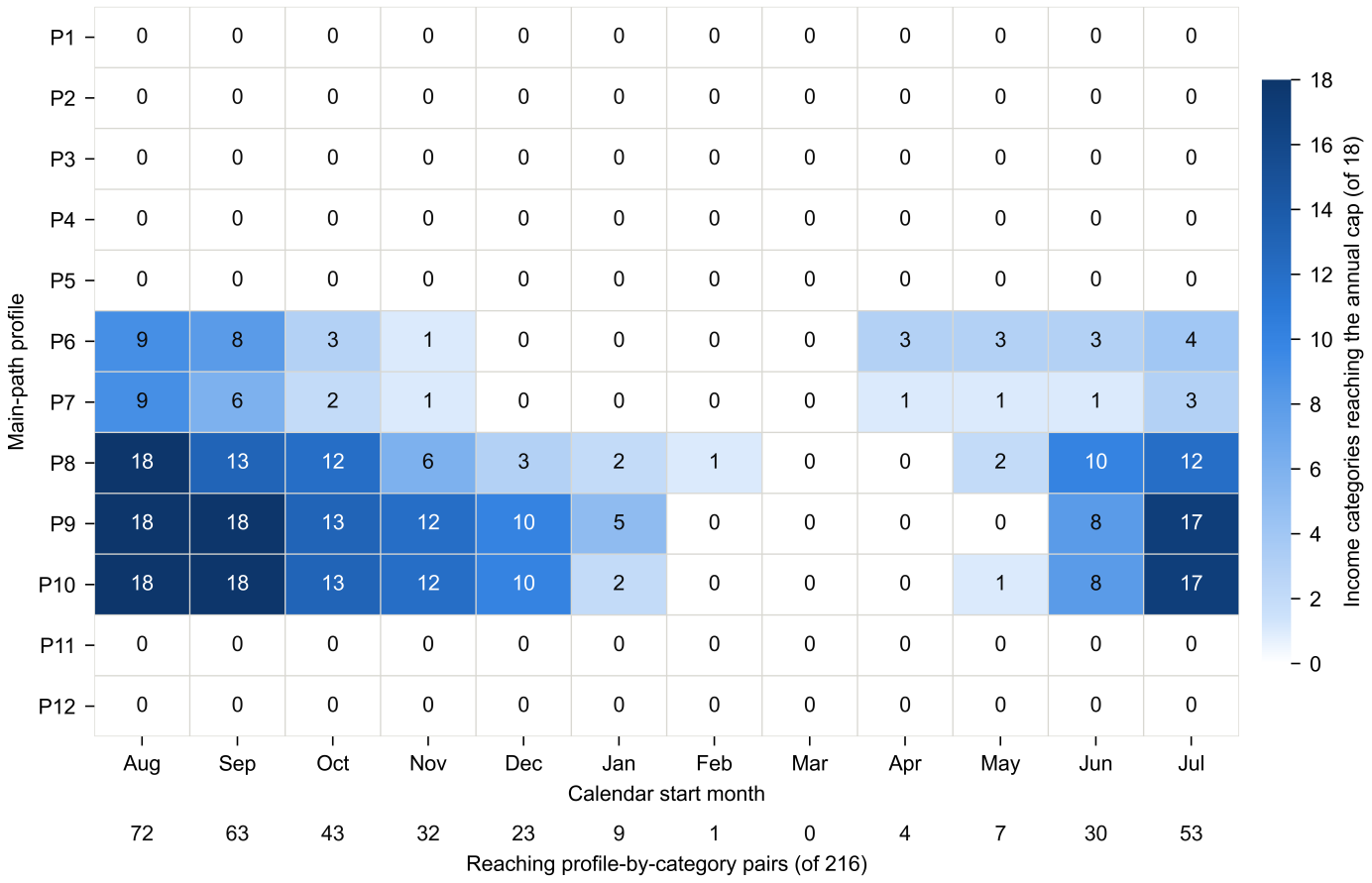
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Before the reform, ordinary month
After the reform, ordinary month
Repeat-month cap in force
Between-caps range
a Category A (highest)
Out-of-pocket payment (thousand JPY)
Between-caps range
467–901 thousand JPY
Total medical expenditure in the month (thousand JPY)
b Category B (upper-middle)
Between-caps range
310–597 thousand JPY
c Category C (middle)
Between-caps range
148–286 thousand JPY
d Category D (lower)
Between-caps range
148–205 thousand JPY
e Category E (municipal-tax-exempt)
Between-caps range
82–123 thousand JPY
f One HER2-positive adjuvant series (P6, base stratum)
Total medical expenditure (thousand JPY)
Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul
Calendar month (treatment starting August)


P1 0 0 0 0 0 0 0 0 0 0 0 0
P2 0 0 0 0 0 0 0 0 0 0 0 0
P3 0 0 0 0 0 0 0 0 0 0 0 0
P4 0 0 0 0 0 0 0 0 0 0 0 0
P5 0 0 0 0 0 0 0 0 0 0 0 0
P6 9 8 3 1 0 0 0 0 3 3 3 4
P7 9 6 2 1 0 0 0 0 1 1 1 3
P8 18 13 12 6 3 2 1 0 0 2 10 12
P9 18 18 13 12 10 5 0 0 0 0 8 17
P10 18 18 13 12 10 2 0 0 0 1 8 17
P11 0 0 0 0 0 0 0 0 0 0 0 0
P12 0 0 0 0 0 0 0 0 0 0 0 0
Main-path profile
Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul
Calendar start month
72 63 43 32 23 9 1 0 4 7 30 53
Reaching profile-by-category pairs (of 216)
Income categories reaching the annual cap (of 18)
0 2 4 6 8 10 12 14 16 18

Supplementary Files

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- AppendixBreastCancerv1420261017.pdf